MAR 1 9 2003 K030621

1075 W. Lambert Road Building D
Brea, California 92821
T (714) 672 3553 **F** (714) 672 3554

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The ATAC Calibrator Kit is intended to calibrate the ATAC Clinical Systems for the quantitative determination of albumin, calcium, cholesterol, creatinine, glucose, magnesium, phosphorus, total bilirubin, total protein and urea nitrogen. The ATAC Calibrator is substantially equivalent to the Beckman Synchron Multi-Calibrator, product no. 465915, which is currently marketed by Beckman Coulter, Inc. of Brea, CA. The effectiveness of ATAC Calibrator Kit on the ATAC 8000 Random Access Chemistry System is shown by the following studies.

The reconstituted stability claim is confirmed through the assay of albumin, magnesium, phosphorus, total bilirubin and total protein in calibrators of increasing ages. The observed changes in the concentrations of albumin, magnesium, bilirubin and total protein over 3 days at 2°C to 8°C were statistically insignificant or less than the round-off error of the assay. The observed change for phosphorus over three days was less than 0.2 mg/dL.

The accuracy of the assigned set points was documented through method comparison studies. At least 50 sera were assayed for albumin, magnesium, phosphorus, total bilirubin and total protein over at least 4 analytical runs using a commercially available method and ATAC reagent applications calibrated with the ATAC Calibrator.

Deming regression statistics are summarized below.

Analyte	Comparative Method	Regression Statistics
Albumin	Hitachi 704 / Roche Albumin Reagent, product 1970569 Roche c.f.a.s Calibrator, product 759350	y = 0.25 + 0.908x, n = 59
Magnesium	Beckman Synchron CX Magnesium Reagent, product 445360 Beckman Synchron Multi Calibrator, product 442600	y = 0.03 + 0.967x, n = 55
Phosphorus	Beckman Synchron CX Phosphorus Reagent, product 465145 Beckman Synchron Multi Calibrator, product 442600	y = -0.10 + 0.992x, n = 58
Total Bilirubin	Beckman Synchron CX Total Bilirubin Reagent, product 442745 Beckman Synchron Bilirubin Calibrator, product 465915	y = -0.06 + 1.031x, n = 54
Total Protein	Beckman Synchron CX Total Protein Reagent, product 442740 Beckman Synchron Multi Calibrator, product 442600	y = 0.00 + 1.000x, n = 52

Wynn Stocking
Manager of Regulatory Affairs
Elan, Brea California

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 9 2003

Mr. Wynn Stocking
Manager of Regulatory Affairs
Elan Diagnostics
1075 W. Lambert Road Building D
Brea, California 92821

Re: k030621
Trade/Device Name: ATAC Calibrator Kit
Regulation Number: 21 CFR § 862.1150
Regulation Name: Calibrator, Multi – Analyte Mixture
Regulatory Class: II
Product Code: JIX
Dated: February 26, 2003
Received: February 27, 2003

Dear Mr. Stocking:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030621

Device Name: ATAC Calibrator

Indications for Use:

The ATAC Calibrator Kit is intended for use with the ATAC Clinical Systems to establish points of reference that are used in the determination of albumin, calcium, cholesterol, creatinine, glucose, magnesium, phosphorus, total bilirubin, total protein and urea in human specimens.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030621

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)